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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MEDA PHARMACEUTICALS INC., Plaintiff, v. APOTEX INC., APOTEX CORP., PERRIGO ISRAEL PHARMACEUTICAL LTD., PERRIGO COMPANY, and L. PERRIGO COMPANY, Defendants.	Civil Action No. _____

COMPLAINT

Plaintiff Meda Pharmaceuticals Inc. ("Meda"), for its Complaint against Defendants Apotex Inc., Apotex Corp., Perrigo Israel Pharmaceutical Ltd. ("Perrigo Israel"), Perrigo Company ("Perrigo Co."), and L. Perrigo Company ("L. Perrigo") (collectively, "Defendants"), hereby alleges as follows:

PARTIES

1. Plaintiff Meda is a Delaware corporation having a principal place of business at 265 Davidson Avenue, Somerset, New Jersey 08873.

2. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

3. Upon information and belief, Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

5. Upon information and belief, Apotex Corp. is a wholly owned affiliate of Apotex Inc. and the United States agent for Apotex Inc. for purposes including, but not limited to, making regulatory submissions to the United States Food and Drug Administration ("FDA").

6. Upon information and belief, Apotex Corp. is the United States marketing and sales agent for Apotex Inc. wherein, following FDA approval of an Abbreviated New Drug Application ("ANDA"), Apotex Inc. manufactures and supplies the approved generic drug products to Apotex Corp., which then markets and sells those products throughout the United States, including in this judicial district, following any FDA approval.

7. Upon information and belief, and consistent with its practice with respect to other generic products, Apotex Inc. will sell the generic product accused of infringement in this Complaint through Apotex Corp. throughout the United States, including in this judicial district, following any FDA approval.

8. Upon information and belief, Apotex Corp. is the United States subsidiary, agent, and alter-ego of Apotex Inc. Upon information and belief, for all purposes relevant to this action, Apotex Inc. and Apotex Corp. are effectively the same entity and are referred to collectively hereinafter as Apotex.

9. Upon information and belief, Defendant Perrigo Israel is an Israeli corporation with a corporate headquarters and place of business at 29 Lehi Street, Bni Brak, 51200, Israel.

10. Upon information and belief, Perrigo Israel is a wholly owned subsidiary, agent, and alter-ego of Perrigo Co. and is under the direction, control, and/or influence of Perrigo Co., both generally and with respect to the conduct alleged in this Complaint.

11. Upon information and belief, Perrigo Israel manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

12. Upon information and belief, Defendant Perrigo Co. is a Michigan corporation having a place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

13. Upon information and belief, Perrigo Co. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

14. Upon information and belief, Perrigo Co. is the United States marketing and sales agent for Perrigo Israel, wherein, following FDA approval of an ANDA, Perrigo Israel manufactures and supplies the approved generic drug products to Perrigo Co., which then markets and sells those products throughout the United States, including in this judicial district, following any FDA approval.

15. Upon information and belief, and consistent with its practice with respect to other generic products, Perrigo Israel will sell the generic product accused of infringement in this Complaint through Perrigo Co. throughout the United States, including in this judicial district, following any FDA approval.

16. Upon information and belief, Defendant L. Perrigo is a Michigan corporation having a place of business at 71 Suttons Lane, Piscataway, New Jersey 08854.

17. Upon information and belief, L. Perrigo is a wholly owned subsidiary, agent, and alter-ego of Perrigo Co.

18. Upon information and belief, for all purposes relevant to this action Perrigo Israel, Perrigo Co., and L. Perrigo are effectively the same entity and are referred to collectively hereinafter as Perrigo.

NATURE OF THE ACTION

19. This is a civil action for the infringement of United States Patent No. 8,071,073 ("the '073 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

JURISDICTION AND VENUE

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

21. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Meda in New Jersey. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

22. This Court has personal jurisdiction over Apotex Inc. by virtue of, *inter alia*: (1) its presence in New Jersey through its United States subsidiary, agent, and alter-ego, Apotex Corp.; and (2) its systematic and continuous contacts with New Jersey.

23. Upon information and belief, Apotex Inc. develops and manufactures generic drugs for sale and use throughout the United States, including this judicial district. Upon

information and belief, Apotex Inc. derives substantial revenue from the sale of Apotex products to customers in New Jersey.

24. As further evidence of personal jurisdiction, Apotex Inc. has availed itself of the protections offered by this district as a plaintiff in litigation. (*See*, *e.g.*, Civil Action Nos. 2:06-cv-01153, 2:08-cv-03598).

25. As further evidence of personal jurisdiction, Apotex Inc. has been sued for patent infringement, and has consented to personal jurisdiction, in this judicial district. (*See*, *e.g.*, Civil Action Nos. 2:06-cv-01153, 3:2007-cv-01000, 2:07-cv-4417, 2:08-cv-03065, 2:08-cv-04053, 1:09-cv-01518, 3:09-cv-05614, 3:09-cv-06373, 2:10-cv-06241, 3:10-cv-05810 and 2:11-cv-03076).

26. This Court has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*: (1) its presence in New Jersey; and (2) its systematic and continuous contacts with New Jersey.

27. Upon information and belief, Apotex Corp. sells numerous generic drugs manufactured and supplied by Apotex Inc. throughout the United States, including this judicial district.

28. Upon information and belief, Apotex Corp. is registered with the New Jersey Department of Health and Senior Services as a "Drug or Medical Device Manufacturing or Wholesale Drug or Medical Device Business" pursuant to N.J.S.A. 24:6B.

29. As further evidence of personal jurisdiction, Apotex Corp. has been sued for patent infringement, and has consented to personal jurisdiction, in this judicial district. (*See*, *e.g.*, Civil Action Nos. 2:06-cv-01153, 3:2007-cv-01000, 2:07-cv-4417, 2:08-cv-03065, 2:08-cv-04053, 1:09-cv-01518, 3:09-cv-05614, 3:09-cv-06373, 2:10-cv-06241, 3:10-cv-05810 and 2:11-cv-03076).

30. This Court has personal jurisdiction over Perrigo Israel by virtue of, *inter alia*: (1) its presence in New Jersey through its United States affiliate, agent, and alter-ego, L. Perrigo; and (2) its systematic and continuous contacts with New Jersey.

31. Upon information and belief, Perrigo Israel develops and manufactures pharmaceutical products for the United States market. Upon information and belief, Perrigo Israel derives substantial revenue from the sale of Perrigo products to customers in New Jersey.

32. As further evidence of personal jurisdiction, Perrigo Israel has stipulated that it is subject to jurisdiction in the District of New Jersey. (*See* Civil Action No. 2:10-cv-0937).

33. This Court has personal jurisdiction over Perrigo Co. by virtue of, *inter alia*: (1) its presence in New Jersey through its United States subsidiary, agent, and alter-ego, L. Perrigo; and (2) its systematic and continuous contacts with New Jersey.

34. Upon information and belief, Perrigo Co. sells numerous generic drugs manufactured and supplied by Perrigo Israel throughout the United States, including this judicial district.

35. Upon information and belief, Defendant Perrigo Co. is licensed with the New Jersey Secretary of State to conduct business in the State of New Jersey.

36. According to its 10K, filed for the fiscal year ended on June 25, 2011, Perrigo Co. reported that "[i]n the U.S., its operations are conducted primarily through L. Perrigo Company…."

37. According to Perrigo Co.'s 2010 Annual Report, its "U.S.-based customers are major wholesalers, including Cardinal Health, McKesson and AmerisourceBergen, as well as national and regional retail drug, supermarket and mass merchandise chains, including Walgreens, Wal-Mart, CVS, Rite Aid" and others. Upon information and belief, Perrigo intends

to sell the generic product at issue in this Complaint through L. Perrigo to these same retail outlets in New Jersey.

38. Upon information and belief, Perrigo Co. directs the activities of the other Perrigo entities, including Perrigo Israel and L. Perrigo, and is directly responsible for sales of Perrigo products to customers in New Jersey through L. Perrigo, from which Perrigo Co. derives substantial revenue.

39. As further evidence of personal jurisdiction, Perrigo Co. has been sued for patent infringement in this district and has not contested personal jurisdiction. (*See*, *e.g.*, Civil Action Nos. 3:06-cv-4715 and 3:08-cv-1909). Perrigo Co. also has admitted to personal jurisdiction, and stipulated that it is subject to jurisdiction, in the District of New Jersey. (*See* Civil Action No. 3:06-cv-4715 and 2:10-cv-0937, respectively).

40. This Court has personal jurisdiction over L. Perrigo by virtue of, *inter alia*: (1) its presence in New Jersey; and (2) its systematic and continuous contacts with New Jersey.

41. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and (d) and 1400(b).

THE PATENT

42. On December 6, 2011, U.S. Patent No. 8,071,073 ("the '073 patent"), titled "Compositions Comprising Azelastine and Methods of Use Thereof," was duly and legally issued to Meda Pharmaceuticals Inc. as assignee. A copy of the '073 patent is attached hereto as Exhibit A.

43. The '073 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for certain Meda Astepro® brand azelastine products.

ACTS GIVING RISE TO THIS ACTION

Count I – Infringement Of The '073 Patent By All Defendants

44. Upon information and belief, on or before December 6, 2011, Defendants submitted ANDA Nos. 20-1846, 09-1556, and 20-2743 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). These ANDAs seek the FDA approval necessary to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of certain Meda Astepro® brand azelastine products. ANDA Nos. 20-1846, 09-1556 and 20-2743 specifically seek FDA approval to market the proposed generic versions of Meda's Astepro® brand azelastine products prior to the expiration of the '073 patent.

45. ANDA Nos. 20-1846, 09-1556, and 20-2743 allege under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '073 patent are either invalid or not infringed by the manufacture, use, or sale of the proposed generic versions of Meda's Astepro® brand azelastine products. Meda received written notification of ANDA Nos. 20-1846, 09-1556 and 20-2743 and their § 505(j)(2)(A)(vii)(IV) allegations during the week of December 5-9, 2011.

46. Defendants' submission of ANDA Nos. 20-1846, 09-1556, and 20-2743 to the FDA, including their § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if any of the defendants commercially makes, uses, offers for sale or sells, or imports into the United States, a proposed generic version of a Meda Astepro® brand azelastine products, or induces or contributes to such conduct, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b), and/or (c).

47. Meda will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Meda does not have an adequate remedy at law.

Count II – Infringement Of The '073 Patent By Defendant Apotex

48. Upon information and belief, on or before December 5, 2011, Apotex submitted ANDA Nos. 20-1846 and 09-1556 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA Nos. 20-1846 and 09-1556 seek the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of generic azelastine hydrochloride nasal spray. ANDA No. 20-1846 specifically seeks FDA approval to market a proposed generic version of Meda's Astepro® (azelastine hydrochloride) Nasal Spray (0.15%, eq. 0.1876 mg base/spray). ANDA No. 09-1556 specifically seeks FDA approval to market a proposed generic version of a product that has been withdrawn from the market, Meda's Astepro® (azelastine hydrochloride) Nasal Spray (0.1%, eq. 0.125 mg base/spray).

49. ANDA Nos. 20-1846 and 09-1556 allege under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '073 patent are either invalid or not infringed by the manufacture, use, or sale of the proposed generic versions of Meda's Astepro® brand azelastine products. Meda first received written notification of ANDA Nos. 20-1846 and 09-1556 and their § 505(j)(2)(A)(vii)(IV) allegations during the week of December 5-9, 2011.

50. Apotex's submission of ANDA Nos. 20-1846 and 09-1556 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex commercially manufactures, uses, offers for sale, or sells, or imports into the United States, its proposed generic versions of Meda's Astepro® brand azelastine products, or induces or contributes to such conduct, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b) and/or (c).

51. Even if Apotex Inc. and Apotex Corp. are not treated as a single entity for the purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '073 patent.

52. Apotex Inc. is jointly and severally liable for infringement of the '073 patent. That is so because, upon information and belief, Apotex Inc. submitted ANDA Nos. 20-1846 and 09-1556 to the FDA under § 505(j) and will, *inter alia*, manufacture, offer to sell, and sell the proposed generic versions of Meda's Astepro® brand azelastine products upon receipt of FDA approval.

53. Apotex Inc.'s submission of ANDA Nos. 20-1846 and 09-1556 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Apotex Inc. commercially makes, uses, offers to sell, or sells, or imports into the United States, the proposed generic versions of Meda's Astepro® brand azelastine products, or induces or contributes to any such conduct during the term of the '073 patent, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b) and/or (c).

54. Apotex Corp. is jointly and severally liable for infringement of the '073 patent, regardless of which Apotex entity actually filed ANDA Nos. 20-1846 and 09-1556 and regardless of whether it is treated as an agent or alter-ego of Apotex Inc. for purposes of this action. This is so because, upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted, and/or induced the submission of ANDA Nos. 20-1846 and 09-1556 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA and will, *inter alia*, import, offer to sell, and sell the proposed generic versions of Meda's Astepro® brand azelastine products within the United States and this judicial district upon receipt of any FDA approval of ANDA Nos. 20-1846 and 09-1556.

55. Apotex Corp.'s participation, contribution to, aiding, abetting, and/or inducement of the submission of ANDA Nos. 20-1846 and 09-1556 and the §505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '073 patent under 35 U.S.C.

§ 271(e)(2)(A). Moreover, if Apotex Corp. commercially makes, uses, offers to sell or sells, or imports into the United States, the proposed generic versions of Meda's Astepro® brand azelastine products, or induces or contributes to any such conduct during the term of the '073 patent, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b) and/or (c).

56. Meda will be irreparably harmed by Defendant Apotex's infringing activities unless those actions are enjoined by this Court. Meda does not have an adequate remedy at law.

Count III – Infringement Of The '073 Patent By Defendant Perrigo

57. Upon information and belief, on or before December 6, 2011, Perrigo submitted ANDA No. 20-2743 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 20-2743 seeks the FDA approval necessary to engage in the commercial manufacture, use, offer for sale and sale of generic azelastine hydrochloride nasal spray. ANDA No. 20-2743 specifically seeks FDA approval to market a proposed generic version of Meda's Astepro® Azelastine Hydrochloride Nasal Spray (0.15%, eq. 0.1876 mg base/spray).

58. ANDA No. 20-2743 alleges under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '073 patent are either invalid or not infringed by the manufacture, use or sale of the proposed generic versions of Meda's Astepro® brand azelastine products. Meda first received written notification of ANDA No. 20-2743 and its § 505(j)(2)(A)(vii)(IV) allegation during the week of December 5-9, 2011.

59. Perrigo's submission of ANDA No. 20-2743 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Perrigo commercially uses, offers for sale, or sells, or imports into the United States, its proposed generic versions of Meda's Astepro® brand azelastine products, or

induces or contributes to such conduct, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b) and/or (c).

60. Even if Perrigo Israel, Perrigo Co., and L. Perrigo are not treated as a single entity for the purposes of this action, which they should be, each of them is nonetheless jointly and severally liable for the infringement of the '073 patent.

61. Perrigo Israel is jointly and severally liable for infringement of the '073 patent. That is so because, upon information and belief, Perrigo Israel submitted ANDA No. 20-2743 to the FDA under § 505(j) and will, *inter alia*, manufacture Perrigo's proposed generic version of Meda's Astepro® brand azelastine products upon receipt of FDA approval.

62. Perrigo Israel's submission of ANDA No. 20-2743 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Perrigo Israel commercially makes, or imports into the United States, Perrigo's proposed generic version of Meda's Astepro® brand azelastine products, or induces or contributes to any such conduct during the term of the '073 patent, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b) and/or (c).

63. Perrigo Co. is jointly and severally liable for infringement of the '073 patent, regardless of which Perrigo entity actually filed ANDA No. 20-2743 and regardless of whether it is treated as an agent or alter-ego of Perrigo Israel and/or L. Perrigo for purposes of this action. This is so because, upon information and belief, Perrigo Co. participated in, contributed to, aided, abetted, and/or induced the submission of ANDA No. 20-2743 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA and will, *inter alia*, make, offer to sell and sell the proposed generic version of Meda's Astepro® brand azelastine products within the United States and this judicial district upon receipt of any FDA approval of ANDA No. 20-2743.

64. Perrigo Co.'s participation, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 20-2743 and the §505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Perrigo Co. commercially makes, uses, offers to sell or sells, or imports into the United States, Perrigo's proposed generic versions of Meda's Astepro® brand azelastine products, or induces or contributes to any such conduct during the term of the '073 patent, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b) and/or (c).

65. L. Perrigo is jointly and severally liable for infringement of the '073 patent, regardless of which Perrigo entity actually filed ANDA No. 20-2743 and regardless of whether it is treated as an agent or alter-ego of Perrigo Israel and/or Perrigo Co. for purposes of this action. This is so because, upon information and belief, L. Perrigo participated in, contributed to, aided, abetted, and/or induced the submission of ANDA No. 20-2743 and the § 505(j)(2)(A)(vii)(IV) allegations to the FDA and will, *inter alia*, offer to sell and sell the proposed generic version of Meda's Astepro® brand azelastine products within the United States and this judicial district upon receipt of any FDA approval of ANDA No. 20-2743.

66. L. Perrigo's participation, contribution to, aiding, abetting, and/or inducement of the submission of ANDA No. 20-2743 and the §505(j)(2)(A)(vii)(IV) allegation to the FDA constitutes infringement of the '073 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if L. Perrigo commercially makes, uses, offers to sell, or sells, or imports into the United States, the proposed generic version of Meda's Astepro® brand azelastine products, or induces or contributes to any such conduct during the term of the '073 patent, it would further infringe the '073 patent under 35 U.S.C. § 271(a), (b) and/or (c).

67. Meda will be irreparably harmed by Defendant Perrigo's infringing activities unless those actions are enjoined by this Court. Meda does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Meda prays for judgment as follows:

A. That all Defendants have infringed the '073 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of any of Defendants' ANDAs identified in this Complaint shall not be earlier than the expiration date of the '073 patent, including any extensions or exclusivities;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the proposed generic versions of Meda's Astepro® brand azelastine products identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '073 patent, prior to the expiration of the '073 patent, including any extensions or exclusivities;

D. That Meda be awarded monetary relief if any Defendant commercially uses, offers for sale, or sells, or imports into the United States, its proposed generic version of a Meda Astepro® brand azelastine product, or any other product that infringes or induces or contributes to the infringement of the '073 patent, within the United States prior to the expiration of that patent, including any extensions or exclusivities, and that such monetary relief be awarded to Meda with prejudgment interest;

E. That Meda be awarded the attorney fees, costs and expenses that it incurs prosecuting this action under 35 U.S.C. §285; and

F. That Meda be awarded such other and further relief as this Court deems just and proper.

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

Meda, by its undersigned counsel, hereby certifies pursuant to L.Civ.R. 11.2 that the matters in controversy are not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: January 19, 2012

Respectfully submitted,

s/ Thomas R. Curtin

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